

Amendments to the Claims:

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

1. (Currently amended) A controlled release oral pharmaceutical composition comprising:
 - a. therapeutically effective amount of one or more pharmacologically active agents showing low bioavailability;
 - b. one or more solubilizers, wherein ratio of the solubilizer to the drug is about 20:1 to about 1:20;
 - c. one or more biocompatible swelling agents[,,]; and
 - d. a swelling enhancer;

wherein the swelling agent in combination with swelling enhancer, swell in the presence of gastric fluid such that the size of the dosage form is sufficiently increased to not pass through the pylorus, thereby providing retention of the dosage form in the stomach of a patient.
2. (Currently amended) The controlled release composition of claim 1 wherein the swelling agent in combination with swelling enhancer, swell in the presence of gastric fluid such that the size of the dosage form is retained in the upper gastrointestinal tract for a time period of up to about 12 hours sufficiently increased to not pass through the pylorus, thereby providing retention of the dosage form in the stomach of a patient, and gradually erode within the gastrointestinal tract over a prolonged time period of up to 24 hours.
3. (Previously presented) The controlled release oral pharmaceutical composition of claim 1, wherein the pharmacologically active agent is selected from the group consisting of: antiulcer, antidiabetic, anticoagulant, antithrombic, hypolipemic, antiarrhythmic, vasodilatory, antianginal, antihypertensive, vasoprotective agents, fertility enhancers, labor inducers and inhibitors, contraceptive, antibiotic, antifungal, antiviral, anticancer, anti-inflammatory, analgesic, antiepileptic, antiparkinsonian, neuroleptic, hypnotic, anxiolytic, psychostimulatory, antimigraine, antidepressant, antitussive, antihistamine or antiallergic agents.

4. (Original) The controlled release oral pharmaceutical composition of claim 1 wherein the pharmacologically active agent is selected from the group consisting of pentoxifylline, prazosin, acyclovir, levodopa, nifedipine, diltiazem, naproxen, , flurbiprofen, ketoprofen, fenoprofen, fentiazac, oestradiol valerate, metoprolol, sulpiride, captopril, cimetidine, zidovudine, nicardipine, terfenadine, salbutamol, carbamazepine, ranitidine, enalapril, simvastatin, fluoxetine, famotidine, ganciclovir, famciclovir, ciprofloxacin, pentazocine, omeprazole, saquinavir, ritonavir, indinavir, nelfinavir, thiamphenicol, calcium carbonate, clarithromycin, azithromycin, ceftazidime, cyclosporine, digoxin, paclitaxel, iron salts, topiramate, and ketoconazole and mixtures thereof.
5. (Canceled)
6. (Original) The controlled release oral pharmaceutical composition of claim 1, wherein the solubilizer is selected from the group consisting of hydrophilic surfactants, lipophilic surfactants and mixtures thereof.
7. (Previously presented) The controlled release oral pharmaceutical composition as claimed in claim 1, wherein the solubilizer is selected from the group consisting of anionic, nonionic, cationic, and zwitterionic surfactants.
8. (Original) The controlled release oral pharmaceutical composition of claim 1, wherein the solubilizer comprises one or more hydrophilic nonionic surfactants selected from the group consisting of polyethylene glycol sorbitan fatty acid esters and hydrophilic transesterification products of a polyol with at least one member of the group consisting of triglycerides, vegetable oils, and hydrogenated vegetable oils.
9. (Previously presented) The controlled release oral pharmaceutical composition of claim 1, wherein the solubilizer is selected from the group consisting of PEG-20-glyceryl stearate, PEG-40 hydrogenated castor oil, PEG 6 corn oil, lauryl macrogol - 32 glyceride, stearoyl macrogol glyceride, polyglyceryl - 10 mono dioleate, propylene glycol oleate, Propylene glycol dioctanoate, Propylene glycol caprylate/caprate, Glyceryl monooleate, Glycerol monolinoleate,

Glycerol monostearate, PEG- 20 sorbitan monolaurate, PEG – 4 lauryl ether, Sucrose distearate, Sucrose monopalmitate, polyoxyethylene-polyoxypropylene block copolymer, polyethylene glycol 660 hydroxystearate, Sodium lauryl sulphate, Sodium dodecyl sulphate, Proylene glycol alginate, sodium taurocholate, sodium glycocholate, sodium deoxycholate, betains, polyethylene glycol, and mixture thereof

10-13. (Canceled)

14. (Previously presented) The controlled release oral pharmaceutical of claim 1, wherein the biocompatible swelling agent is selected from the group consisting of: polyalkylene oxides; cellulosic polymers; acrylic acid and methacrylic acid polymers, and esters thereof, maleic anhydride polymers; polymaleic acid; poly(acrylamides); poly(olefinic alcohol)s; poly(N-vinyl lactams); polyols; polyoxyethylated saccharides; polyoxazolines; polyvinylamines; polyvinylacetates; polyimines; starch and starch-based polymers; polyurethane hydrogels; chitosan; polysaccharide gums; zein; shellac-based polymers; and copolymers and mixtures thereof.

15. (Previously presented) The controlled release oral pharmaceutical composition of claim 1, wherein the biocompatible swelling agent is one or more hydrophilic polymers selected from the group consisting of polyethylene oxide, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, hydroxyethyl cellulose, sodium carboxy methylcellulose, calcium carboxymethyl cellulose, methyl cellulose, polyacrylic acid, maltodextrin, pre-gelatinized starch, polyvinyl alcohol and mixtures thereof.

16. (Currently amended) The controlled release oral pharmaceutical composition of claim [[1]] 15, wherein one or more hydrophilic polymers is selected from the group consisting of poly(ethylene oxide), poly(ethylene oxide-co-propylene oxide), and mixtures thereof.

17. (Currently amended) The controlled release oral pharmaceutical composition of claim [[1]] 15, wherein the hydrophilic polymer is poly(ethylene oxide).

18. (Previously presented) The controlled release oral pharmaceutical composition of claim 1, wherein the content of the hydrophilic polymer in the polymer matrix is about 5 to about 90 weight percent.
19. (Currently amended) The controlled release oral pharmaceutical composition of claim [[1]] 15, wherein the weight percent of the hydrophilic polymer in the polymer matrix is about 10 to about 70 .
20. (Canceled)
21. (Previously presented) The controlled release oral pharmaceutical composition of claim 1, wherein the swelling enhancer is selected from the group consisting of low-substituted hydroxypropyl cellulose, microcrystalline cellulose, cross-linked sodium or calcium carboxymethyl cellulose, cellulose fiber, cross-linked polyvinyl pyrrolidone, cross-linked polyacrylic acid, cross-linked functionalized polystyrene or polyacrylic acid resin, alginates, colloidal magnesium-aluminum silicate, corn starch granules, rice starch granules, potato starch granules, pregelatinized starch, sodium carboxymethyl starch and mixtures thereof.
22. (Currently amended) The controlled release oral pharmaceutical composition of claim 1, wherein the swelling enhancer is selected from the group consisting of cross-linked sodium, calcium carboxymethyl cellulose, cross-linked polyvinyl pyrrolidone, sodium carboxymethyl starch, pregelatinised pregelatinized starch and mixtures thereof.
23. (Previously presented) The controlled release oral pharmaceutical composition of claim 1, wherein the swelling enhancer is a cross-linked polyvinyl pyrrolidone.
24. (Previously presented) The controlled release oral pharmaceutical composition of claim 1, wherein the content of the swelling enhancer is about 5 to about 90 weight percent.
25. (Previously presented) The controlled release oral pharmaceutical composition of claim 1, wherein the content of the swelling enhancer is about 10 to about 70 weight percent.

26. (Canceled)

27. (Currently amended) A pharmaceutical dosage form in the form of an expanding a swelling multi-layered system comprising
a first layer having at least one active pharmaceutical ingredient with an immediate release property; and
a second layer having at least one active pharmaceutical ingredient with a sustained release property, one or more solubilizers, one or more biocompatible swelling agents and a swelling enhancer.

28. (Original) The pharmaceutical dosage form according to claim 27 wherein the ratio of said active ingredient in said first layer to said active ingredient in said second layer in the range of from about 10:90 to about 90:10 by weight.

29. (Previously presented) The solid pharmaceutical composition for oral administration according to claim 27 wherein said first layer further comprises a disintegrating agent selected from group consisting of starch, sodium starch glycolate, pregelatinized starch, crosslinked poly vinyl pyrrolidone, cross linked carboxy methyl cellulose, ion exchange resin and mixtures thereof.

30. (Currently amended) The solid pharmaceutical composition for oral administration according to claim [[28]] 29 wherein said disintegrating agent is present in an amount ranging from about 0.25% to about 10%, based on the total weight of the composition.

31. (Original) A process for preparing a pharmaceutical composition comprising the steps of solubilizing an active pharmaceutical active ingredient with one or more solubilizers; and incorporating said solubilized active agent in a gastroretentive matrix having one or more swelling agents and one or more swelling enhancers.

32. (Canceled)